

Remarks:

The Claims are 13-24. A listing of the claims has not been included because this response does not include a change to an existing claim, cancellation of a claim or submission of a new claim.

Double Patenting rejections:

Claims 13-21 are provisionally rejected on nonstatutory obviousness-type double patenting over copending Application No. 09/745,776. Applicants respectfully request reconsideration in light of the accompanying Terminal Disclaimer. The fee should be deducted from OSI Pharmaceuticals, Inc. Deposit Account No. **50-2783**. Applicants respectfully submit that the claims are now allowable and request a Notice to that effect.

Applicants have not received back the 1449 form, initialed by the Examiner to show that the references have been considered, from the IDS submitted with this application. Applicants respectfully request the Examiner initial the form, after each reference has been considered, and return the initialed form to Applicants. For the Examiner's convenience, copies of the IDS submissions from the parent case are enclosed.

Commissioner is authorized to charge any deficiencies in fees and credit any overpayment to OSI Pharmaceuticals, Inc. Deposit Account No. **50-2783**.

Very truly yours,



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July 19, 2006
OSI Pharmaceuticals, Inc.
41 Pinelawn Road
Melville, NY 11747

TRANSMITTAL OF INFORMATION DISCLOSURE STATEMENT
(Under 37 CFR 1.97(b) or 1.97(c))

Docket No.
20784/4

4/2/01

In Re Application of: Demuth, et al

APR 02 2001

Serial No.

Filing Date

December 22, 2000

Examiner

NOT YET ASSIGNED

Group Art Unit

NOT YET ASSIGNED

Title: **PRODRUGS OF DP IV INHIBITORS**

Address to:
Assistant Commissioner for Patents
Washington, D.C. 20231

37 CFR 1.97(b)

1 ☒ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10 ☐ 11 ☐ 12 ☐ 13 ☐ 14 ☐ 15 ☐ 16 ☐ 17 ☐ 18 ☐ 19 ☐ 20 ☐ 21 ☐ 22 ☐ 23 ☐ 24 ☐ 25 ☐ 26 ☐ 27 ☐ 28 ☐ 29 ☐ 30 ☐ 31 ☐ 32 ☐ 33 ☐ 34 ☐ 35 ☐ 36 ☐ 37 ☐ 38 ☐ 39 ☐ 40 ☐ 41 ☐ 42 ☐ 43 ☐ 44 ☐ 45 ☐ 46 ☐ 47 ☐ 48 ☐ 49 ☐ 50 ☐ 51 ☐ 52 ☐ 53 ☐ 54 ☐ 55 ☐ 56 ☐ 57 ☐ 58 ☐ 59 ☐ 60 ☐ 61 ☐ 62 ☐ 63 ☐ 64 ☐ 65 ☐ 66 ☐ 67 ☐ 68 ☐ 69 ☐ 70 ☐ 71 ☐ 72 ☐ 73 ☐ 74 ☐ 75 ☐ 76 ☐ 77 ☐ 78 ☐ 79 ☐ 80 ☐ 81 ☐ 82 ☐ 83 ☐ 84 ☐ 85 ☐ 86 ☐ 87 ☐ 88 ☐ 89 ☐ 90 ☐ 91 ☐ 92 ☐ 93 ☐ 94 ☐ 95 ☐ 96 ☐ 97 ☐ 98 ☐ 99 ☐ 100 ☐ 101 ☐ 102 ☐ 103 ☐ 104 ☐ 105 ☐ 106 ☐ 107 ☐ 108 ☐ 109 ☐ 110 ☐ 111 ☐ 112 ☐ 113 ☐ 114 ☐ 115 ☐ 116 ☐ 117 ☐ 118 ☐ 119 ☐ 120 ☐ 121 ☐ 122 ☐ 123 ☐ 124 ☐ 125 ☐ 126 ☐ 127 ☐ 128 ☐ 129 ☐ 130 ☐ 131 ☐ 132 ☐ 133 ☐ 134 ☐ 135 ☐ 136 ☐ 137 ☐ 138 ☐ 139 ☐ 140 ☐ 141 ☐ 142 ☐ 143 ☐ 144 ☐ 145 ☐ 146 ☐ 147 ☐ 148 ☐ 149 ☐ 150 ☐ 151 ☐ 152 ☐ 153 ☐ 154 ☐ 155 ☐ 156 ☐ 157 ☐ 158 ☐ 159 ☐ 160 ☐ 161 ☐ 162 ☐ 163 ☐ 164 ☐ 165 ☐ 166 ☐ 167 ☐ 168 ☐ 169 ☐ 170 ☐ 171 ☐ 172 ☐ 173 ☐ 174 ☐ 175 ☐ 176 ☐ 177 ☐ 178 ☐ 179 ☐ 180 ☐ 181 ☐ 182 ☐ 183 ☐ 184 ☐ 185 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☐ 1159 ☐ 1160 ☐ 1161 ☐ 1162 ☐ 1163 ☐ 1164 ☐ 1165

TRANSMITTAL OF INFORMATION DISCLOSURE STATEMENT
(Under 37 CFR 1.97(b) or 1.97(c))

Docket No.
20784/4

In Re Application Of Demuth, et al

APR 10 2 2001

Serial No.

09/24/00

Filing Date

December 22, 2000

Examiner

NOT YET ASSIGNED

Group Art Unit

NOT YET ASSIGNED

Title: PRODRUGS OF DP IV INHIBITORS

Payment of Fee

(Only complete if Applicant elects to pay the fee set forth in 37 CFR 1.17(p))

- ☐ A check in the amount of _____ is attached.
- ☒ The Assistant Commissioner is hereby authorized to charge and credit Deposit Account No. _____ as described below. A duplicate copy of this sheet is enclosed.
- ☐ Charge the amount of _____
- ☐ Credit any overpayment.
- ☐ Charge any additional fee required.

Certificate of Transmission by Facsimile*

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Certificate of Mailing by First Class Mail

I certify that this document and fee is being deposited on March 29, 2001 with the U.S. Postal Service as first class mail under 37 C.F.R. 1.8 and is addressed to the Assistant Commissioner for Patents, Washington, D.C. 20231.

Signature of Person Mailing Correspondence

Renee M. Mason

Typed or Printed Name of Person Mailing Correspondence

*This certificate may only be used if paying by deposit account.

Dated: March 29, 2001

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CC:

2/25/03

Notice of References Cited	Application/Control No. 09/745,776	Applicant(s)/Patent Under Reexamination DEMUTH ET AL.	
	Examiner B. Dell Chism	Art Unit 1654	Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
	A	US-			
	B	US-			
	C	US-			
	D	US-			
	E	US-			
	F	US-			
	G	US-			
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FOREIGN PATENT DOCUMENTS

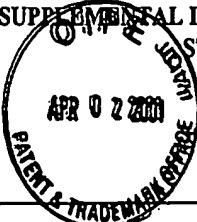
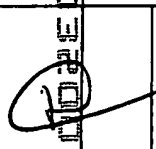

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	N					
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NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	Tanaka et al. 1997. Suppression of Arthritis by the Inhibitors of Dipeptidyl Peptidase IV. Int. J. Immunopharmac., Vol. 19, No 1, pp. 15-24, see abstract, pp. 18-19.
	V	Augustyns et al. 1997. Pyrrolidides: synthesis and structure-activity relationship as inhibitors of dipeptidyl peptidase IV. Eur J Med Chem, Vol. 32, pp. 301-309, see abstract.
	W	
	X	

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

2/25/03

FORM PTO-1449 SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT			ATTY DOCKET NO. 20784/4		SERIAL NO. 09/745,776	
			APPLICANT(S): Demuth et al.			
			FILING DATE: December 22, 2000		ART UNIT: Not yet Assigned	
UNITED STATES PATENT DOCUMENTS						
EXAM. INITIAL	DOCUMENT NUMBER	DATE	INVENTOR	CLASS	SUB CLASS	FIL. DATE IF APPR
FOREIGN PATENT DOCUMENTS						
DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB CLASS	TRAN Y/N	
OTHER DOCUMENTS (INCLUDING AUTHOR, TITLE, DATE, PERTINENT PAGES, ETC.)						
CF 	WAKSELMAN, M., NGUYEN, C., MAZALEYRAT, J.-P., CALLEBAUT, C., KRUST, B., HOVANESSIAN, A.G., Inhibition of HIV-1 infection of CD 26+ but not CD26-cells by a potent cyclopeptidic inhibitor of the DPP IV activity of CD 26. Abstract P 44 of the 24th European Peptide Symposium 1996.					
Examiner: 			Date: 21 February 2003			



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Attorney Docket No. 20784/4

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT: Demuth et al.

U.S.S.N.: 09/745,776

Art Unit: 1614

FILED: 12/22/2000

Examiner: Not yet assigned

FOR: *PRODRUGS OF DP IV INHIBITORS*

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CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service as express mail in an envelope addressed to Assistant Commissioner for Patents, Washington, D.C. 20231 on April 27, 2001.

By: 

Michelle M. Guinazzo

**SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT
(SUBMISSION AFTER FILING OF AN APPLICATION
BUT BEFORE FIRST ACTION ON THE MERITS)**

Honorable Commissioner of Patents and Trademarks
Washington, D.C. 20231

Date April 27, 2001

Sir:

Pursuant to 37 C.F.R. §§ 1.97 and 1.98, applicant(s) hereby submit(s) an Information Disclosure Statement for consideration by the Examiner. Copies of the listed items are enclosed.

The citation of the listed items is not a representation that they constitute a complete or exhaustive listing of the relevant art or that the references are prior art. The items listed are submitted in good faith, but are not intended to substitute for the Examiner's search. It is hoped, however, that in addition to apprising the Examiner of these particular items, they will assist in identifying fields of search and in making as full and complete a search as possible.

The filing of this information disclosure statement is not an admission that the information cited herein is, or is considered to be, material to patentability as defined in 37 C.F.R. § 1.56(b).

I. LIST OF PATENTS, PUBLICATIONS OR OTHER INFORMATION

The patents, publications or other information submitted for consideration by the Office are listed on PTO-1449, attached hereto.

II. COPIES

- a. ☒ Submitted herewith is a legible copy of (i) each U.S and foreign patent; (ii) each publication or that portion which caused it to be listed; and (iii) all other information or that portion which caused it to be listed.

III. CONCISE EXPLANATION OF THE RELEVANCE

(check at least one box)

- a. ☐ Except as may be indicated below in (b), all of the patents, publications or other information are in the English language or were cited in an English language Search Report, a copy of which is attached hereto (concise explanation not required).

- b. ☒ A concise explanation of the relevance of all patents, publications or other information listed that are not in the English language are as follows:

FRENCH LANGUAGE FR 2 696 740 apparently relates to Dimethylbiguanide drug derivatives and their medical applications.

FRENCH LANGUAGE FR 2 085 655 apparently relates to biguanide substitutes possessing a hypoglycemic property.

GERMAN LANGUAGE DT 25 42598 A1 apparently relates to biguanide salts as well as a method for preparing such salts. In addition to this the invention apparently covers pharmaceutical compounds which contain such salts.

GERMAN LANGUAGE WO97/40832 apparently relates to the use of a method for reducing in the blood of a mammal by administration of effectors the enzyme activity of dipeptidyl peptidase (DP IV) or enzyme activity similar to DP IV, the endogenous (or additionally exogenously administered) insulinotropic peptide gastric inhibitory polypeptide 1-42 and glucagon-like peptide amide-1 7-36 are decomposed in a causal sequence to a reduced extent by DP IV enzymes or those similar to DP IV.

JAPANESE PATENT JP 4334357A2: ACYL DERIVATIVE HAVING ENZYME-INHIBITING ACTION, apparently relates to a compound having a prolyl endopeptidase activity-inhibiting action and useful as an antidement agent, especially an anti-amnestic agent.

GERMAN PATENT DD296075A5: VERFAHREN ZUR HERSTELLUNG NEUER INHIBITOREN DER DIPEPTIDYL PEPTIDASE IV, apparently relates to the preparation of preparing new inhibitors of dipeptidyl peptidase IV by synthesizing an aminoacid amide of formula A-B (I) from XAY or XA(Z)Y and B utilizing conventional peptide chemistry methods for forming amide bonds (See Derwent Abstract).

- c. ☐ The following additional information is provided for the Examiner's consideration:

FEES

IV. THIS IDS IS BEING FILED UNDER 37 C.F.R. § 1.97(b)
(check one box)

- a. ☐ within three months of the filing date of a national application (37 C.F.R. § 1.97(b) (1)). No fee or certification is required.
- b. ☐ within three months of the date of entry of the national stage as set forth in §1.491 in an international application (37 C.F.R. § 1.97(b) (2)). No fee or certification is required.
- c. ☒ before the mailing date of a first Action on the merits (37 C.F.R. § 1.97(b) (3)). No fee or certification is required. In the event that a first Office Action on the merits has been issued, please consider this IDS under 37 C.F.R. § 1.97(c) and see the certification under 37 C.F.R. § 1.97(e) below, or, if no certification has been made, charge our deposit account a fee in the amount of \$180.00 as required by 37 C.F.R. § 1.17(p).

V. THIS IDS IS BEING FILED UNDER 37 C.F.R. § 1.97(c):
(check one box)

before the mailing date of a Final Office Action under 37 C.F.R. § 1.113 (See 37 C.F.R. § 1.97(c) (1)) or before the mailing date of a Notice of Allowance under 37 C.F.R. § 1.311 (See 37 C.F.R. § 1.97(c) (2)).

- a. ☐ No certification; therefore, a check in the amount of \$180.00 is enclosed as required by 37 C.F.R. . § 1.17(p).

or

- b. ☐ See the certification below. No fee is required.

VI. CERTIFICATION UNDER 37 C.F.R. § 1.97(e) (check only one box)

The undersigned hereby certifies that

- a. ☐ each item of information contained in the IDS was cited in a communication from a foreign Patent Office in a counterpart foreign application not more than three months prior to the filing of this IDS; or
- b. ☐ no item of information contained in the IDS was cited in a communication from a foreign Patent Office in a counterpart foreign application or, to the best of my knowledge after making reasonable inquiry, was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of this statement.
- c. ☐ Some of the items of information were cited in a communication from a foreign Patent Office. As to this information, the undersigned certifies that each item of information contained in the IDS was cited in a communication from a foreign Patent Office in a counterpart foreign application not more than three months prior to the filing of this IDS. As to the remaining information, the undersigned hereby certifies that no item of this remaining information contained in the IDS was cited in a communication from a foreign Patent Office in a counterpart foreign application or, to the best of my knowledge after making reasonable inquiry, was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of this statement.

☐ Please charge deposit account 50-0369 in the amount of \$180.00 for the above-indicated fee. A duplicate copy of this paper is attached.

☒ No fee is required.

If the Examiner has any questions concerning this IDS, he/she is requested to contact the undersigned. If it is determined that this IDS has been filed under the wrong rule, the PTO is requested to consider this IDS under the proper rule (with a petition, if necessary) and charge the appropriate any additional fees to Deposit Account No. 50-0369.


IDS USSN: 09/745,776

Page 5

The claims of the application as now presented are believed to patentably distinguish over the prior art and to be in condition for allowance. Early and favorable consideration of this application are respectfully requested.

Respectfully submitted,

Date: April 27, 2001



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4/30/01

FORM PTO-1449
INFORMATIONAL DISCLOSURE STATEMENT

ATTY DOCKET NO.
20784/4

SERIAL NO.
09/745,776

APPLICANT(S): Demuth et al.

FILING DATE:
12/22/2000

ART UNIT:
1614

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UNITED STATES PATENT DOCUMENTS

EXAM. INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB CLASS	FIL. DATE IF APPR
(D)	AA	2,961,377	11-1960	Shapiro et al.	167	65	
	AB	3,960,949	6-1976	Ahrens et al.	260	564 B	
	AC	4,935,493	6-1990	Bachovchin et al.	530	331	
	AD	5,433,955	7-1995	Bredehorst et al.	424	94.3	
	AE	5,512,549	4-1996	Chen et al.	514	12	
	AF	5,614,379	3-1997	MacKellar	435	68.1	
	AG	5,624,894	4-1997	Bodor	514	2	
(D)	AH	6,006,753	12-1999	Efendic	128	898	8/21/97

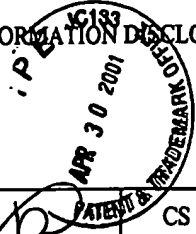
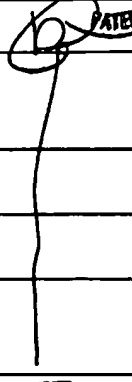

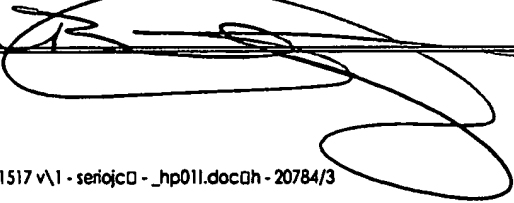
FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB CLASS	TRAN YES/NO
(D)	BD	WO 00/53171	9-14-00	PCT	A61K	31/155	Y
* No Translation	BE	DT 25 42598 A1	10-11-74	DE	C07C	139/16	N
* No Translation	BF	FR 2696740	10-13-92	FR	C07D	207/404	N
* No Translation	BG	FR 2085665	3-3-71	FR	A61K	27/00	N
(D)	BH	WO 93/08259 A2	4/29/93	PCT	G12N		Y
	BI	WO 95/11689	5/4/95	PCT	A61K	37/00	Y
	BJ	EP 0 708 179 A2	10/13/95	EPO	G12N	15/16	Y
	BK	0 658 568 A1	12/2/94	EPO	C07K	14/605	Y
	BL	WO 97/45117	12/4/97	PCT	A61K	31/435	Y
	BM	WO 97/40832	11/6/97	PCT	A61K	31/425	Abstract only
(D)	BN	WO 95/15309	6/8/95	PCT	C07D	207/16	Y
* No Translation	BO	DD 0 296 075	11/21/91	DD			N
(D)	BP	JP 4334357 A2	11/20/92	JP	C07C	233/57	Abstract only

* Considered 24 February 2003

FORM PTO-1449		ATTY DOCKET NO.	SERIAL NO.
INFORMATION DISCLOSURE STATEMENT		20784/4	09/745,776
		APPLICANT(S): Demuth et al.	
		FILING DATE: 12/22/2000	ART UNIT: 1614
OTHER DOCUMENTS (INCLUDING AUTHOR, TITLE, DATE, PERTINENT PAGES, ETC.)			
	CC	Campbell, I.W., Sulphonylureas and metformin: efficacy and inadequacy. 3:33-51 (1990).	
	CD	Merck Index, 11 th Edition, Page 934	
	CE	Martindale the Extra, Pharmacopoeia, Page 1619	
	CG	J. Lin et al.: "Inhibition of depeptidyl peptidase IV by fluoroolefin-containing n-peptidyl-O-hydroxylamine peptidomimetics" PROCEEDINGS OF THE NATIONAL ACADEMY OF SCIENCES OF USA, Vol. 95, November 1998 (1998-11)	
	CH	KOROM, S. et al., Inhibition of CD26/dipeptidyl peptidase IV activity in vivo prolongs cardiac allograft survival in rat recipients, Transplantation Vol. 63, pg 1495-1500, Nov. 10, 1997	
	CI	TANAKA, S. et al., Suppression of arthritis by the inhibitors of dipeptidyl peptidase IV. Int. J. Immunopharmacol. Vol. 19, No. 1, Pg 15-24 (1997)	
	CJ	WETZL, W. et al., Effects of the CLIP fragment ACTH 20-24 on the duration of REM sleep episodes. Neuropeptides, 31, (1), Pg 41-45 (1997)	
	CK	THORENS, B et al., Glucagon-Like Peptide-I and the Control of Insulin Secretion in the Normal State and in NIDDM. Diabetes 42:1219-1225 (1993)	
	CL	ORSKOV C. et al., Proglucagon Products in Plasma of Noninsulin-dependent Diabetics and Nondiabetic Controls in the Fasting State and After Oral Glucose and Intravenous Argine. J. Clin. Invest. 87:415-423 (1991)	
	CM	PAULY, R. et al., Improved Glucagon Tolerance in Rats Treated with the Dipeptidyl Peptidase IV (CD26) Inhibitor ILE-Thaxolidide. Metabolism 48:385-389 (1999)	
	CN	GUTNIAK, M. K. et al., Subcutaneous Injection of the Incretin Hormone Glucagon-Like Peptide 1 Abolishes Postprandial Glycemia in NIDDM. Diabetes Care 17:1039-1044, (Sept. 1994)	
	CO	CHEMICAL ABSTRACTS, vol. 115, No. 15, 14. Oktober 1991 (1991-10-14) Columbus, Ohio, US; abstract no. 149947q, SCHOEN EKKEHARD ET AL: "Dipeptidyl peptidase IV in the immune system. Effects of specific enzyme inhibitors on activity of dipeptidyl peptidase IV and proliferation of human lymphocytes" Seite 37; XP002114197 Zusammenfassung & BIOL. CHEM. HOPPE-SEYLER, Bd. 372, Nr. 5, 1991, Seiten 305-311,	
	CP	CHEMICAL ABSTRACTS, vol. 126, no. 2, 13. Januar 1997 (1997-01-13) Columbus, Ohio, US; abstract no. 16161j, STOECKEL A. ET AL: "Competitive inhibition of proline specific enzymes by amino acid thioxopyrrolidides and thiazolidides" Seite 241; XP002114198 Zusammenfassung & PEPT: CHEM., STRUCT.BIOL., PROC.AM.PEPT.SYMP., Nr. 14, 1995, Seiten 709-710,	
	CQ	CHEMICAL ABSTRACTS, vol. 118, no. 25, 21. Juni 1993 (1993-06-21) Columbus, Ohio, US; abstract no. 255342k, Seite 933; XP002114199 Zusammenfassung & JP 04 334357 A (FUJERE BIO INC) 20. November 1992 (1992-11-20)	
	CR	ARAI, H. ET AL: "Synthesis of prolyl endopeptidase inhibitors and evaluation of their structure-activity relationships : in vitro inhibition of prolyl endopeptidase" CHEMICAL AND PHARMACEUTICAL BULLETIN., Bd. 41, Nr. 9, 1993	

21. February 2003

FORM PTO-1449		ATTY DOCKET NO.	SERIAL NO.
INFORMATION DISCLOSURE STATEMENT 		20784/4	09/745,776
		APPLICANT(S): Demuth et al.	
		FILING DATE: 12/22/2000	ART UNIT: 1614
	CS	WINSLOW, R., Novartis Drug Alters Picture for Diabetes. <i>Wall Street Journal</i> , Wed. Dec. 27, 2000, p. B2.	
	CT	WILLMS, B. et al., Gastric Emptying, Glucose Response, and Insulin Secretion after a Liquid Test Meal: Effects of Exogenous Glucagon-Like Peptide-1 (GLP-1)-(7-36) Amide in Type 2 (Noninsulin-Dependent) Diabetic Patients. <i>JCEM</i> 81:327332 (1996) No. 1 327-332	
	CU	HENDRICK, G.K. et al., Glucagon-Like Peptide-I-(7-37) Suppresses Hyperglycemia in Rats. <i>Metabolism</i> Vol. 42, No. 1, pg 1-6 (Jan. 1993)	
	CV	DEACON, C. et al., Degradation of Glucagon-Like Peptide-1 by Human Plasma in Vitro an N-Terminally Truncated Peptide that is a Major Endogenous Metabolite in Vivo. <i>JCEM</i> 80:952-957, (April 25, 1995)	
	CW	HOFFMAN, T. et al., Inhibition of Dipeptidyl Peptidase IV (DPIV) by anti-DP IV antibodies and non-substrate X-X-Pro- Oligopeptides Ascertained by Capillary Electrophoresis. <i>Journal of Chromatography A</i> , 716 355-362 (1995)	
	CX	NAUCK, M.A. et al., Normalization of Fasting Hyperglycaemia by Exogenous Glucagon-Like Peptide I (7-36 Amide) in Type 2 (Non-insulin-dependent) Diabetic Patients. <i>Diabetologia</i> 36:741-744 (1993)	
Examiner: 		Date: 21 February 2003	



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Docket No. 2078474 1 8 2002

TECH CENTER 1600/2900

#10

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT: Demuth, et al.

ART UNIT: 1614

SERIAL NO.: 09/745,776

FILED: December 22, 2000

FOR: PRODRUGS OF DP IV INHIBITORS

CERTIFICATE OF MAILING

I hereby certify that this paper (along with any paper referred to as being attached or enclosed) is being deposited with the United States Postal Service on the date shown below with sufficient postage as first class mail in an envelope addressed to the: Assistant Commissioner for Patents, Washington, D.C. 20231-0001

By: Carmen M. Constantinescu

Date: June 7, 2002

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Assistant Commissioner for Patents
Washington, D.C. 20231

Date: June 7, 2002

Pursuant to Applicant(s) duty of disclosure, the information listed in the attached form PTO-1449 is brought to the attention of the Examiner. Copies of the listed items are enclosed.

The citation of the listed items is not a representation that they constitute a complete or exhaustive listing of the relevant art or that the references are prior art. The items listed are submitted in good faith, but are not intended to substitute for the Examiner's search. It is hoped, however, that in addition to apprising the Examiner of these particular items, they will assist in identifying fields of search and in making as full and complete a search as possible.

The filing of this information disclosure statement is not an admission that the information cited herein is, or is considered to be, material to patentability as defined in 37 C.F.R. § 1.56(b).

In accordance with the requirement under 37 C.F.R. 1.98 (3)(i), the following are concise explanations of the relevance, as presently understood, with regard to those items submitted herewith that are not in the English language:

I. LIST OF PATENTS, PUBLICATIONS OR OTHER INFORMATION

The patents, publications or other information submitted for consideration by the Office are listed on PTO-1449, attached hereto.

II. COPIES

- a. ☒ Submitted herewith is a legible copy of (i) each U.S and foreign patent; (ii) each publication or that portion which caused it to be listed; and (iii) all other information or that portion which caused it to be listed

III. CONCISE EXPLANATION OF THE RELEVANCE
(check at least one box)

- a. ☐ Except as may be indicated below in (b), all of the patents, publications or other information are in the English language or were cited in an English language Search Report, a copy of which is attached hereto (concise explanation not required).

- b. ☒ A concise explanation of the relevance of all patents, publications or other information listed that is not in the English language is as follows:

German language EP 0 995 440 A1 : A method of raising the blood sugar level in a mammal having hypoglycemia is described. The method reduces degradation of glucagon by administering to the mammal a therapeutically effective amount of an inhibitor of dipeptidyl peptidase IV and physiologically acceptable adjuvants and/or excipients.

- c. ☐ The following additional information is provided for the Examiner's consideration:

FEES

IV. THIS IDS IS BEING FILED UNDER 37 C.F.R. § 1.97(b)
(check one box)

- a. ☐ within three months of the filing date of a national application (37 C.F.R. § 1.97(b) (1)). No fee or certification is required.

- b. ☐ within three months of the date of entry of the national stage as set forth in §1.491 in an international application (37 C.F.R. § 1.97(b) (2)). No fee or certification is required.
- c. ☒ **before the mailing date of a first Action on the merits (37 C.F.R. § 1.97(b) (3)). No fee or certification is required.** In the event that a first Office Action on the merits has been issued, please consider this IDS under 37 C.F.R. § 1.97(c) and see the certification under 37 C.F.R. § 1.97(e) below, or, if no certification has been made, charge our deposit account a fee in the amount of \$180.00 as required by 37 C.F.R. § 1.17(p).

V. THIS IDS IS BEING FILED UNDER 37 C.F.R. § 1.97(c):
(check one box)

before the mailing date of a Final Office Action under 37 C.F.R. § 1.113 (See 37 C.F.R. § 1.97(c) (1)) or before the mailing date of a Notice of Allowance under 37 C.F.R. § 1.311 (See 37 C.F.R. § 1.97(c) (2)).

- a. ☐ No certification; therefore, a fee in the amount of \$180.00 is required by 37 C.F.R. § 1.17(p).
- or
- b. ☐ See the certification below. No fee is required.

VI. CERTIFICATION UNDER 37 C.F.R. § 1.97(e) (check only one box)

The undersigned hereby certifies that

- a. ☐ each item of information contained in the IDS was cited in a communication from a foreign Patent Office in a counterpart foreign application not more than three months prior to the filing of this IDS; or
- b. ☐ no item of information contained in the IDS was cited in a communication from a foreign Patent Office in a counterpart foreign application or, to the best of my knowledge after making reasonable inquiry, was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of this statement.
- c. ☐ Some of the items of information were cited in a communication from a foreign Patent Office as indicated in the Form 1449 by those references having an asterisk(*). As to this information, the undersigned certifies that each item of information contained in the IDS was cited in a

communication from a foreign Patent Office in a counterpart foreign application not more than three months prior to the filing of this IDS. As to the remaining information, the undersigned hereby certifies that no item of this remaining information contained in the IDS was cited in a communication from a foreign Patent Office in a counterpart foreign application or, to the best of my knowledge after making reasonable inquiry, was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of this statement.

- ☐ A check in the amount of \$180.00 is enclosed for the above-indicated fee. A duplicate copy of this paper is attached.
- ☒ No fee is required.

VII. THIS IDS IS BEING FILED UNDER 37 C.F.R. § 1.704(d) (PATENT TERM ADJUSTMENT)


Applies to original applications (other than design) filed on or after May 29, 2000.

- a. _____ Each item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart application and this communication was not received by any individual designated in § 1.56© more than thirty days prior to the filing of the Information Disclosure Statement.
- b. X Enclosed herewith is form PTO-1449.
- c. X Copies of cited references are enclosed.
- d. _____ The listed references were cited in the enclosed International Search Report in a counterpart foreign application.

If the Examiner has any questions concerning this IDS, he/she is requested to contact the undersigned. If it is determined that this IDS has been filed under the wrong rule, the PTO is requested to consider this IDS under the proper rule (with a petition, if necessary) and charge the appropriate any additional fees to Deposit Account No. 50-0369.

Respectfully submitted,

Date: June 7, 2002



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Reg. No. 39,023
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Attorney for Applicants
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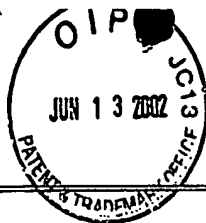
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JUN 18 2002

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FORM PTO-1449 INFORMATION DISCLOSURE STATEMENT				ATTY DOCKET NO. 20784/4		SERIAL NO. 09/745,776	
				APPLICANT(S): Demuth et al.			
				FILING DATE: December 22, 2000		ART UNIT: 1614	
UNITED STATES PATENT DOCUMENTS							
EXAM. INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB CLASS	FIL. DATE IF APPR
	AA	3,174,901	3/23/65	Sterne	167	65	
	AB	3,879,541	4/22/1975	Kabbe et al.	424	326	
	AC	4,028,402	6/7/1977	Fischer et al.	260	501.14	
	AD	5,462,928	10/31/95	Bachovchin et al.	514	19	
	AE	5,543,396	8/6/96	Powers et al.	514	19	
	AF	5,939,560	8/17/99	Jenkins et al.	548	535	
FOREIGN PATENT DOCUMENTS							
		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB CLASS	TRAN YES/NO
	BA	WO 01/62266 A2	08/30/01	PCT	A61K	38/00	Y
	BB	WO 00/01849	01/13/00	PCT	C12Q	1/68	Y
	BC	DD 296 075 A5	11/21/91	Germany	C07D	295/04	Y
	BD	EP 0 995 440 A1	4/26/00	EPO	A61K	31/425	N
	BE	WO 91/11457	08/8/91	PCT	C07K	7/34	Y
	BF	WO 91/16339	10/31/91	PCT	C07K	5/10	Y
	BG	WO 98/19998	5/14/98	PCT	C07D	207/00	Y
	BH	WO 91/17767	11/28/91	PCT	A61K	37/54	Y
	BI	JP 04-288098	10/13/92	JP	C07K	7/06	(Abstract Only)

21 Feb 2003




JUN 18 2002

TECH CENTER 1600/2900

FORM PTO-1449 INFORMATION DISCLOSURE STATEMENT	ATTY DOCKET NO. 20784/4	SERIAL NO. 09/745,776
	APPLICANT(S): Demuth et al.	
	FILING DATE: December 22, 2000	ART UNIT: 1614

OTHER DOCUMENTS (INCLUDING AUTHOR, TITLE, DATE, PERTINENT PAGES, ETC.)		
CA	The Merck Index, 12 th Edition, An Encyclopedia of Chemicals, Drugs, and Biologicals, 1996, Page 1014.	
CB	Martindale The Extra Pharmacopoeia, 30 th Edition, London Pharmaceutical Press, 1993, Page 36.	
CC	DURINX, C.; et al.; "Reference Values for Plasma Dipeptidyl-Pepidase IV activity and their Association with Other Laboratory Parameters". Clin Chem Lab Med 2001, February; 39 (2) :155-9, 1 page.	
CD	GOSSRAU, R.; "Cytochemistry of Membrane Proteases". Histochem J, 1985, July; 17 (7) :737-71, 1 page.	
CE	HAHN, T.; et al.; "Enzyme Histochemical Evidence for the Presence of Potential Blood Pressure Regulating Proteases in Cultured Villous Explants from Human First Trimester Placentae". Acta Histochem 1993, December, 1995 (2) :185-92, 1 page.	
CF	HEYMANN, E.; et al.; "Has Dipeptidyl Peptidase IV an Effect on Blood Pressure and Coagulation." Klin Wochenschr, 1984, January, 2;62 (1) :2-10, 1 page.	
CG	MAGYAR, C.E.; et al.; "Proximal Tubule Na Transporter Responses are the same during Acute and Chronic Hypertension." Am J Physiol Renal Physiol, 2000, August; 279 (2) :F358-69, 1 page.	
CH	PAPIES, B.; et al.; "Isoenzyme (Lactate Dehydrogenase, Aspartate Aminotransferase) and Dipeptidyl Peptidase IV Activity Changes in Blood Plasma Likely Indicative of Organ Involvement due to Arterial Hypertension." Cor Vasa, 1991; 33 (3) :218-26, 1 page.	
CI	QURESHI, N.U.; et al., "Endogenous Neuropeptide Y Mediates Vasoconstriction during Endotoxic and Hemorrhagic Shock". Regul Pept, 1998, September 25; 75-76:215-20, 1 page.	
CJ	Index Nominum, International Drug Directory 1992/1993, Medpharm Scientific Publishers, pages 728-729.	
CK	The Merck Index, An Encyclopedia of Chemicals and Drugs, 9 th Edition, Merck & Co., Inc., 1976, page 773.	
CL	C.J. Bailey et al., <u>New Antidiabetic Drugs</u> , Smith-Gordon Nishimura, 1990, p. 36.	
CM	C.B. Welch, <u>Medical Management of Non-Insulin-Dependent (Type II) Diabetes</u> , 3 rd edition, American Diabetes Association, "Diagnosis and Classification" p. 3, 1994, Pharmacologic Intervention (1 page).	
CN	Mannucci et al., <u>Diabetes Care</u> , "Effect of Metformin on Glucagon-Like Peptide 1 (GLP-1) and Leptin Levels in Obese Nondiabetic Subjects", 24(3): 489-494, March 2001.	
CO	Stryer, <u>Biochemistry 3rd Ed.</u> , "Protein Conformation, Dynamics, and Function", 1988, p 191-193.	

 21 Feb 2003



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JUN 18 2002

FORM PTO-1449 INFORMATION DISCLOSURE STATEMENT	ATTY DOCKET NO. 20784/4		TECH CENTER 1600/2900 SERIAL NO. 09/745,776
	APPLICANT(S): Demuth et al.		
	FILING DATE: December 22, 2000	ART UNIT: 1614	

OTHER DOCUMENTS (INCLUDING AUTHOR, TITLE, DATE, PERTINENT PAGES, ETC.)

h	CP	Pauly et al., <u>Regulatory Peptides</u> , "Abstracts Issue: Abstracts from the 11 th International Symposium on Regulatory Peptides", July 15, 1996, 64(1-3): 148 plus cover.
	CQ	Gutniak et al., <u>New England Journal of Medicine</u> , "Antidiabetogenic Effect of Glucagon-like peptide-1 (7-36) Amide in Normal Subjects and Patients With Diabetes Mellitus", 1992, 326: 1316-1322.
	CR	H.A. Smith et al., <u>Veterinary Pathology</u> (fourth edition), "Diseases and Disorders of Metabolism: Deficiency Diseases", 1972, p 1018-1020.
	CS	G.G. Duncan, <u>Diseases of Metabolism (Asian edition)</u> , "Diabetes Mellitus", 1966, p 951-957.
	CT	T.J. Kieffer et al., "Degradation of Glucose-Dependent Insulinotropic Polypeptide and Truncated Glucagon-Like Peptide 1 In Vitro and In Vivo by DP IV", <u>Endocrinology</u> , Vol. 136(8), 1995, p 3585-3596.
	CU	C.F. Deacon et al., <u>Diabetes</u> , "Both Subcutaneously and Intravenously Administered Glucagon-Like Peptide I Are Rapidly Degraded from the NH ₂ -Terminus in Type II Diabetic Patients and in Healthy Subjects", September 1995, 44: 1126-1131.
	CV	<u>Vidal</u> , 1993, 69 th Edition, p. 612-613.
	CX	<u>Goodman & Gilman's The Pharmacological Basis of Therapeutics</u> , Ninth Edition, 1996, p. 1510.
	CY	Nathan et al., <u>Diabetes Care</u> , "Insulinotropic Action of Glucagonlike Peptide-1-(7-37) in Diabetic and Nondiabetic Subjects", February 1992, 15(2): 270-275.
	CZ	<u>Pschyrembel</u> , <u>Kininisches Wörterbuch</u> 257, Auflage, 1994, 9 pages.
	CAA	Frohman et al., <u>Journal of Clin. Invest.</u> , "Rapid Enzymatic Degradation of Growth Hormone-releasing Hormone by Plasma in Vitro and in Vivo to a Biologically Inactive Product Cleaved at the NH ₂ Terminus", Volume 78, October 1986, p 906-913
	CAB	Snow et al., <u>Advances In Medicinal Chemistry</u> , "Boronic Acid Inhibitors of Dipeptidyl Peptidase IV: A New Class of Immunosuppressive Agents", Vol. 3, 1995, p 149-177.
n	CAC	Ashworth et al., <u>BIOORG. MED. CHEM. LETT.</u> , "2-Cyanopyrrolidides as Potent, Stable Inhibitors of Dipeptidyl Peptidase IV", 1996, 6(10): 1163-1166.

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FORM PTO-1449 INFORMATION DISCLOSURE STATEMENT	ATTY DOCKET NO. 20784/4	SERIAL NO. 09/745,776
	APPLICANT(S): Demuth et al.	
	FILING DATE: December 22, 2000	ART UNIT: 1614

OTHER DOCUMENTS (INCLUDING AUTHOR, TITLE, DATE, PERTINENT PAGES, ETC.)

	CAD	Endroczi et al., <u>ACTA PHYSIOL. HUNG.</u> , "Dipeptidyl peptidase IV (DP IV) and Superoxide Dismutase Activity in Thymus-Derived Lymphocytes: Effects of Inhibitory Peptides and Zn ²⁺ in Vitro", 1990, 75(1): 35-44.
	CAE	Lee, H.S. et al., "Cathepsin B Inhibitory Peptides Derived from β -Casein," Peptides 21 (2000) 807-809.
	CAF	Edwards, J.V. et al., <u>J. Peptide Res.</u> , "Synthesis and Activity of NH ₂ - and COOH-Terminal Elastase Recognition Sequences on Cotton," 1999, 54: 536-543.
Examiner:		Date: 21 Feb 2003



USCO 3/23/01

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT(s): Demuth, et al. EXAMINER: Not Yet Assigned
SERIAL NO.: 09/745,776 GROUP: Not Yet Assigned
FILED: December 22, 2000 DOCKET: 20784/4
FOR: PRODRUGS OF DP IV INHIBITORS

CERTIFICATE OF MAILING UNDER 37 C.F.R. §1.8(a)

I hereby certify that this correspondence (along with any paper referred to as being attached or enclosed) is being deposited with the United States Postal Service as first class mail, postpaid in an envelope, addressed to the: Assistant Commissioner of Patents, Washington, D.C. 20231 on March 20, 2001.

Renee Mason-Salewala
Renee M. Mason-Salewala

Assistant Commissioner for Patents
Washington, D.C. 20231

INFORMATION DISCLOSURE STATEMENT

Sir:

Pursuant to Applicant(s) duty of disclosure, the information listed in the attached form PTO-1449 is brought to the attention of the Examiner. Copies of the listed items are enclosed.

The citation of the listed items is not a representation that they constitute a complete or exhaustive listing of the relevant art or that the references are prior art. The items listed are submitted in good faith, but are not intended to substitute for the Examiner's search. It is hoped, however, that in addition to apprising the Examiner of these particular items, they will assist in identifying fields of search and in making as full and complete a search as possible.

The filing of this information disclosure statement is not an admission that the

information cited herein is, or is considered to be, material to patentability as defined in 37 C.F.R.

§ 1.56(b).

In accordance with the requirement under 37 C.F.R. 1.98 (3)(i), the following are concise explanations of the relevance, as presently understood, with regard to those items submitted herewith that are not in the English language:

GERMAN LANGUAGE DE 196 16 486 apparently relates to the use of a method in which reducing in the blood of a mammal, by administration of effectors, the enzyme activity of dipeptidyl peptidase (DP IV) or enzyme activity similar to DP IV causes the blood sugar level to drop below the glucose concentration, characteristic of hyperglycemia, in the serum of the treated organism, preventing or alleviating metabolic anomalies such as glucosuria, hyperlipidemia, possible serious metabolic acidosis, diabetes mellitus which result from higher concentrations of glucose in the blood.

- ☐ This information disclosure statement is being filed within three (3) months of the filing date of this application.
- ☒ **This information disclosure statement is being filed within three (3) months of the date of entry of the national stage as set forth in 37 C.F.R. § 1.491 in an international application.**
- ☒ **To the best of Applicant(s) knowledge, this information disclosure statement is being filed before the date of mailing of a first Office Action on the merits in connection with this case.**
- ☐ Enclosed herewith is a certificate under 37 C.F.R. § 1.97(e)(1).
- ☐ Enclosed herewith is a petition under 37 C.F.R. § 1.97(d)(ii).
- ☐ Enclosed by check is the petition fee of \$130.00.
(37 C.F.R. § 1.17(I)(1))

- ☐ Please charge the \$130.00 petition fee to Deposit Account No. 50-0369.
- ☐ Enclosed by check is the \$240.00 fee required by 37 C.F.R. §1.17(p).
- ☐ Please charge the \$240.00 fee required by 37 C.F.R. § 1.17(p) to Deposit Account No. 04-1121.
- ☒ Please charge any deficiency as well as any other fee(s) which may become due under 37 C.F.R. §1.16 and/or §1.17 at any time during pendency of this application, or credit any overpayment of such fee(s) to Deposit Account 50-0369. Also, in the event any extensions of time for responding and/or a petition under 37 C.F.R. §1.17 are required for the pending application(s), please treat this paper as a petition to extend the time and/or enter this Information Disclosure Statement as required and charge Deposit Account No 50-0369 therefor. **TWO (2) COPIES OF THIS SHEET ARE ENCLOSED.**

The claims of the application as now presented are believed to patentably distinguish over the prior art and to be in condition for allowance. Early and favorable consideration of this application are respectfully requested.

Respectfully submitted,


Mark A. Hofer

Reg. No. 30,068

Attorney for Applicants

Brown, Rudnick, Freed & Gesmer, P.C.

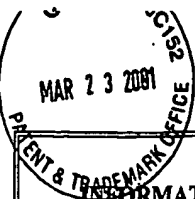
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FORM PTO-1449 INFORMATION DISCLOSURE STATEMENT				ATTY DOCKET NO. 20784/4		SERIAL NO. 09/745,776	
				APPLICANT(S): Demuth et al.			
				FILING DATE: December 22, 2000		ART UNIT: Not yet Assigned	
UNITED STATES PATENT DOCUMENTS							
EXAM. INITIAL		DOCUMENT NUMBER	DATE	INVENTOR	CLASS	SUB CLASS	FIL. DATE IF APPR
FOREIGN PATENT DOCUMENTS							
		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB CLASS	TRAN Y/N
	BA	19616486	10/30/97	DE	A61K	39/395	
	BB	9529691	11/09/95	WO	A61K	031/675	
	BC	9822494	5/28/98	WO	C07K	005/00	
OTHER DOCUMENTS (INCLUDING AUTHOR, TITLE, DATE, PERTINENT PAGES, ETC.)							
	CA	MENTLEIN, R., DAHMS, P., GRANDT, D., KRUGER, R., Proteolytic processing of neuropeptide Y and peptide YY by dipeptidyl peptidase IV. Regul. Pept. 49, 133 (1993)					
	CB	AMASHEH, S., WENZEL, U., WEBER, W.M., CLAUSS, W., DANIEL, H., Electrophysiological analysis of the function of the mammalian renal peptide transporter expressed in Xenopus Laevis oocytes. J. Physiol. 504, 169-174 (1997)					
Examiner:				Date: 21 February 2002			